

REMARKS

Reconsideration and allowance are respectfully requested in light of the above amendments and the following remarks.

Applicant acknowledges with appreciation the indication in the Office Action that claims 20 and 31 contain allowable subject matter. Also, the sole rejection of claim 40 is under 35 USC 112, second paragraph. Claim 40 has been amended to overcome this rejection and is deemed to be in allowable condition.

Claim 29 has been amended to overcome the rejection under 35 USC §112, second paragraph.

The amendments to claims 29 and 40 are considered to be non-narrowing. Therefore, no estoppel should be deemed to attach to these claims.

Further, these non-narrowing claim amendments do not raise any new issues and thus this amendment should be entered 37 CFR 1.116.

To overcome the objection to the drawings, a new Fig. 7 is attached, which illustrates the subject matter of claim 40, lines 12-15. The specification has been amended to describe Fig. 7. Support for Fig. 7 and the amendment to the specification is found at least in the original specification on page 4, lines 24-31.

Claims 18, 19, 22, 26, 27, 29, 30, 33, 37, and 38 stand rejected under 35 USC §102(b) as being anticipated by Goicoechea et al. (US 5,609,627) and under 35 USC §103(a) as being obvious over

Goicoechea. Claims 23, 28, 34, and 39 stand rejected under 35 USC §103(a) as being obvious over Goicoechea. Claims 21, 24, 25, 32, 35, and 36 stand rejected under 35 USC §103(a) as being obvious over Goicoechea in view of Lau (US 5,873,906). Applicant respectfully traverses these rejections.

Claim 18 recites:

*A structure of a prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage, said structure comprising:*

*at least one mesh which, at least in part, is approximately cylindrical and comprises at least one corrugated filament forming approximately annular units linked together, at least some corrugations of said corrugated filament of two respective adjacent units of said annular units being linked together by a plurality of linking means, wherein at least some of said linking means comprise links which are made as a rigid piece,*

*wherein each of said links is provided with a sole central portion and two loops, one loop at each of the ends of said central portion,*

*wherein each of said two loops allows (a) a first shape of an arc of a circle prior to linking and (b) a second shape of an entirely closed loop, in the linking position,*

*wherein each of the two closed loops of each of said links entraps, in said linking position, with some clearance, a respective one of two of said corrugations, which are to be linked together.*

With regard to the anticipation rejection of claim 18, Goicoechea fails to disclose the claimed features wherein: (1) each of the links is provided with a sole central portion and two loops, one loop at each of the ends of the central portion, (2) each of the two loops allows (a) a first shape of an arc of a circle prior

to linking and (b) a second shape of an entirely closed loop, in the linking position, and (3) each of the two closed loops of each of the links entraps, in the linking position, with some clearance, a respective one of two of the corrugations, which are to be linked together.

The Office Action states that Goicoechea discloses a stent formed by zigzag-shaped nitinol filaments that form approximately annular units linked together by links/loops 99c, rings 99d, or staples 99e (Office Action, section 1, lines 4-9). Continuing, the Office Action states that "a staple connection is well known to include one single/sole straight central portion connecting two loops at both ends of the central portion" (Office Action, section 1, lines 9-10).

It is well-settled that anticipation exists only if every element of the claimed invention, as arranged in the claim, is disclosed either expressly or inherently by a single prior art reference. See *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Further, if an allegation of inherent anticipation is

made by the Office, MPEP 2112 requires that it be supported by a *prima facie* case providing "objective evidence" or "cogent technical reasoning" tending to show that the allegedly inherent subject matter is *necessarily*, and not merely *possibly*, present in the cited reference. It is submitted that the applied prior art neither expressly nor inherently discloses the subject matter of the present claims.

Goicoechea does not expressly disclose that the staple connection necessarily has one single/sole straight central portion connecting two loops at both ends of the central portion. The Office Action appears to acknowledge the absence of such an express disclosure by stating the missing disclosure is "well known" to one of ordinary skill in the art. Therefore, the statements of the Office Action seem to imply that the missing disclosure is inherently disclosed by Goicoechea.

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. See *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), MPEP §2112, 3<sup>rd</sup>

paragraph. In relying upon a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art. See *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990), MPEP §2112, 4<sup>th</sup> paragraph. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993), MPEP §2112, 3<sup>rd</sup> paragraph.

In general, it may be possible for staples, such as those used in an office environment, to have a single straight central portion connecting two loops at both ends of the central portion. However, it is also possible for these staples to have a central straight portion and two end portions that bend at about a 180-degree angle, so that the respective ends overlap the central portion and lie substantially flat against it. It is also possible for stapler to be arranged so that, after stapling, the ends of the staples extend away from the center part of the staple. It is also possible for construction staples to have a central straight portion and two 90 degree bends near the opposite ends of the straight portion. A construction staple of this type secures an object, such as a wire, to another object such as a wood stud.

The Office Action does not provide a basis in fact or technical reasoning to reasonably support the determination that the inherent characteristic (i.e., staples having two loops at opposite ends) necessarily flows from the teaching of Goicoechea. As described above, a staple may secure two objects together by means other than enclosing a first object in a first loop, formed at one end of a central portion, and enclosing a second object in a second loop formed at an opposite end of the central portion. Because the extrinsic evidence does not make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art, the implied inherency theory fails to meet the evidentiary standard that is required to support a *prima facie* case of anticipation.

Moreover, Goicoechea's Fig. 4F and written description, when considered together, appear to disclose a means of securing apices 22 of two hoops 20 that is contrary to that posited in the Office Action. As illustrated in Goicoechea's Fig. 4F, the staple appears to form a single loop in the form of a squashed oval circuit. And this interpretation of the illustration is supported by Goicoechea's express disclosure.

Goicoechea discloses that an apex 22 of each hoop 20 is secured to a juxtaposed apex 22 of a neighboring hoop 20 (col. 9,

lines 43-50). The securing means may be a staple 99e formed of wire, as shown in Fig 4F.

The American Heritage College Dictionary, fourth edition, 2002, defines the word "juxtapose" as "to place side by side." This same dictionary defines side by side to mean "next to each other" and defines "next" to mean "nearest in space or position." A first object that is located nearest in space or position to a second object is necessarily in contact with the second object. Based on these definitions, Goicoechea discloses that the two neighboring hoops 20 are in contact with one another when secured by staple 99e, and this is exactly how Goicoechea illustrates the structure.

Goicoechea's Fig. 4F shows the neighboring hoops 20 in contact with each other. Also shown by this figure is a staple 99e encircling the two hoops 20. This staple forms a single closed loop circuit surrounding the two hoops 20.

Goicoechea's disclosed structure is not identical or even similar to Applicant's claimed structure. Claim 18 recites a linking means that has a sole central portion and two loops, with each loop formed at a separate end of the central portion. Additionally, claim 18 recites that each loop entraps a separate one of two corrugations that are to be linked together. The claimed structure makes it impossible for the two corrugations to

touch at the points where they are secured and substantially encircled by the linking means loops. By contrast to the claimed structure, Goicoechea discloses that the apices of the two hoops 20 secured by staple 99e do touch when staple 99e secures them.

Furthermore, with regard to staple 99e, the Office Action states the following. Since the flexibility of a stent is required to facilitate the deployment of the device, Goicoechea's staples "should be partially or entirely closed loops to entrap the zigzag-shaped wire with some clearance" (Office Action, page 3, lines 10-15).

The Office Action does not assert that Goicoechea expressly discloses providing clearance between the entrapped wires and the staples. To the contrary, the Office Action states that some clearance should be provided to give the stent flexibility.

If the Office Action is positing that the knowledge attributed to one of ordinary skill in the art would lead such a person to modify Goicoechea's disclosed structure, Applicant submits that such an argument is inappropriate for an anticipation rejection. On the other hand, if the Office Action is positing that Goicoechea inherently discloses providing clearance between the staple loop and the entrapped wire, Applicant submits that a statement as to what "should be" does not meet the requisite legal standard for substantiating a theory of inherency.



In accordance with the above discussion, Applicant submits that Goicoechea fails to disclose all of the features of claim 18 either expressly or inherently. Therefore, allowance of claim 18 and all claims dependent therefrom is warranted.

Independent claim 29 recites the same features discussed above in connection with the rejection to claim 18. Claim 29 similarly stands rejected as being anticipated by Goicoechea. For at least the same reasons provided with respect to the rejection of claim 18, Applicant submits that Goicoechea does not disclose all of the features recited by claim 29. Therefore, allowance of claim 29 and all claims dependent therefrom is warranted.

With regard to the obviousness rejections to independent claims 18 and 29, the Office Action relies on the same reasoning for the rejections of these claims as provided for the anticipation rejections. However, the Office Action states, in essence, that if Goicoechea does not inherently disclose providing clearance between the staple 99e and the filament wire forming hoop 20, then it would have been obvious to one of ordinary skill in the art to modify Goicoechea's disclosed structure in this way (Office Action, page 3, line 10, through page 4, line 3). The basis for this conclusion is that such a modified structure would provide a linking means allowing flexibility of Goicoechea's structure during its

deployment in a tortuous passage (Office Action, page 4, lines 3-5).

When applying 35 USC §103, the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986); MPEP §2141. To prevent such use of impermissible hindsight, the prior art must provide a motivation to combine the references that create the case of obviousness. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457, 1458 (Fed. Cir. 1998). Stated another way, the prior art must provide the motivation to make the claimed combination. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) ("[A] proper analysis under §103 requires, *inter alia*, consideration of...whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device....").

Goicoechea does not describe providing flexibility or suppleness for the purpose of deploying a stent in a tortuous passage. Moreover, Goicoechea does not recite any form of the root word "flex" in the disclosure.

However, Goicoechea does disclose making the stent resiliently compressible so that it can be implanted in an artery with the aid of a catheter. Specifically, Goicoechea discloses that the sinuous configuration of each turn 20 of the wire skeleton of stent 10

allows the prosthesis to be compressed resiliently radially inwards so that it can be received in a catheter for per cutaneous or cut down delivery to an intra luminal site in the infra renal section of the aortic artery (col. 10, lines 45-50). Goicoechea's structure does not rely on Applicant's claimed structure to provide its resilient compressibility and provides no suggestion to make the modification proposed in the Office Action.

In an exemplary but non-limiting embodiment of the invention illustrated by Fig. 2, Applicant discloses a link 6A-6C made of a rigid piece and having two loops B1 and B2 (specification, page 8, lines 29-31). Each of the loops B1 and B2 entraps, with some clearance J, one of the corrugations or parts of filament F that are to be linked together (specification, page 8, lines 31-33). The entrapment and clearance provided by links B1 and B2 allow the filaments to turn freely (specification, page 8, lines 33-37). Thereby, the link is very supple due to the clearance J and the separation between the two parts of filament F, which have been linked together (specification, page 9, lines 5-8).

The separation between the two filament parts provides the link with two axes of rotation, with each axis of rotation formed by an entrapped filament part. These two axes of rotation provide the link its great flexibility, and the distance between the two axes determines the degree of flexibility.

Applicant respectfully submits that the teaching and motivation to make the claimed combinations may be found only through the impermissible hindsight afforded by the present application. The Office Action provides no evidentiary support for the conclusion that the claimed combinations are suggested or motivated by the prior art. Absent some actual suggestion or motivation provided by the prior art for making the proposed modification, Goicoechea's disclosure and the proposed modification are not properly combinable to render the present claimed invention obvious. As a result, it is respectfully submitted that a *prima facie* case of obviousness has not been established.

Applicant further submits that the distinguishing features discussed above in connection with the anticipation rejection to claim 18 similarly distinguish claims 18 and 29 from Goicoechea, with regard to the obviousness rejection. For brevity, that discussion is incorporated here by reference rather than by repetition.

In accordance with the above discussion, Applicant submits that Goicoechea fails to disclose or suggest all of the features of claims 18 and 29 and the benefits accruing from them. Therefore, allowance of claims 18 and 29 and all claims dependent therefrom is warranted.

Applicant further submits that Goicoechea's staples are very different from the claimed links for the following reasons.

1) A staple 99e has only one loop and does not have a central portion, whereas the claimed link has two loops and a central portion.

2) A staple entraps two corrugations, whereas the claimed link has two loops that each entrap a separate corrugation. Thus, the claimed link improves the suppleness of the structure by preventing the two corrugation filaments from rubbing together and by separating the two corrugations with some distance.

3) Staples 99e have limited suppleness since they firmly grip the filament, whereas the claimed links entrap the corrugations with a certain amount of clearance in the loops. Thus, the filaments can move around in the loops and thereby make the structure very supple. This makes it possible to avoid permanent creases which often exist in known connecting means, once the structure has been folded between its various possible positions. These permanent creases can reduce the cross-sectional area of the passageway that is to be created using the implanted prosthesis.

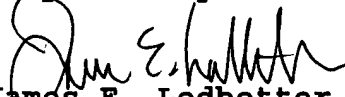
4) Prior to linking, a staple 99e has the shape of a U, whereas the loop of the claimed link has the shape of an arc of a circle.

5) The fitting of a staple 99e is liable to damage the filament. This is not the case with the claimed link because the fitting is different and the loops entrap the corrugations with clearance.

In view of the above, it is submitted that this application is in condition for allowance, and a notice to that effect is respectfully solicited.

If any issues remain which may best be resolved through a telephone communication, the Examiner is requested to telephone the undersigned at the local Washington, D.C. telephone number listed below.

Respectfully submitted,

  
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Exhibit I

29. A structure of a prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage, said structure comprising:

at least one mesh which, at least in part, is approximately cylindrical and comprises at least one corrugated filament forming approximately annular units linked together, at least some of the corrugations of said corrugated filament of two respective adjacent units of said annular units being linked together by a plurality of linking means, wherein at least some of said linking means comprise links which are made as a rigid piece,

wherein each of said links is provided with (a) a single central portion, and (b) two loops comprising one loop at each of the ends of said central portion, wherein each of said two loops allows a first shape of an arc of a circle prior to linking and a second shape of a partially closed loop that is just closed up to entrap the corrugation that is to be linked, in the linking position, and

wherein each of the two loops of each of said links entraps, in said linking position, with [said] a clearance, a respective one of two of said corrugations, which are to be linked together.

40. A structure of a prosthesis intended to be implanted in a human or animal passage to provide through-passage along said passage, said structure comprising:

at least one mesh which, at least in part, is approximately cylindrical and comprises at least one corrugated filament forming approximately annular units linked together, at least some corrugations of said corrugated filament of two respective adjacent units of said annular units being linked together by a plurality of linking means, wherein at least some of said linking means comprise links which are made as a rigid piece,

wherein each of said links is provided with (a) a single central portion, and (b) more than two loops which are connected to said central portion, wherein each of said loops allows a first shape of an arc of a circle prior to linking and a second shape of a closed loop in the linking position, and

wherein each of the two loops of each of said links entraps, in said linking position, with [said] a clearance, a respective one of two of said corrugations, which are to be linked together.